PCORI Workshop on Long-Term Opioid Treatment for Chronic Pain

Workgroup Discussion Questions - Group 2

Consolidated General Questions - Categories

1	**Studies that Include Non-pharmacologic Options**
2	**Risk Assessment and Risk Mitigation Strategies**
3	**Other**

Evidence Gap: The current evidence base for the use of long-term opioids (>3 months) for chronic pain and the effectiveness of different risk assessment/risk mitigation strategies is extremely weak, given the importance of this topic.

Objective: Identify, refine, and prioritize comparative effectiveness research questions that focus on long-term treatment of chronic pain.

Considerations:

Patients with chronic noncancer pain >3 months Outcomes >1 year
Randomized controlled design vs. an observational study
Studies must be long enough to observe important outcomes.
Subgroups proposed and others to consider: • High risk patient populations • Low socioeconomic status or poor access to healthcare • Sex • Racial and ethnic minorities

Original (refined) questions

1	**Studies that Include Non-pharmacologic Options:** In patients with chronic pain, what is the comparative effectiveness and risks of opioids plus non-pharmacological options versus opioids or non-opioid interventions alone on outcomes related to pain, function, quality of life, and doses of opioids used? *Potential patient populations may include:* patients with chronic low back pain, musculoskeletal pain, fibromyalgia, neuropathic pain; substance abusers, those recently incarcerated, pregnant women, cancer survivors etc. *Alternative non-pharmacological options may include*: physical therapy, behavioral therapy proven complementary and alternative medicine approaches etc.
1.1	What are the comparative benefits and risks of a multimodal approach (PT, injections, cognitive behavioral therapy) and non-opioid analgesics versus long term opioid analgesics for adults with chronic pain? Outcome measures include quality of life (QOL) indices (better mobility, better sleep, better mood, improved daily function) and pain reduction).

1.2	What are the comparative benefits and risks of a combined approach using yoga, mind body practice and non-opioid analgesics versus long term opioid analgesics in patients with chronic generalized pain? Outcome measures include QOL indices (better mobility, sleep, mood, function) and pain reduction.
1.3	What is the impact of parallel vs. sequential timing of multimodal/integrative pain treatment (including opioids and non-pharmacologic treatments) on measures of pain and functional status in patients with chronic pain, stratified by treatment modality and underlying disease state?
1.4	1) Improving long-term function and pain in opioid-using persons with chronic pain **a. Population:** Patients with chronic non-cancer musculoskeletal pain. (3+ months) prescribed >1 month opioid therapy (consider a minimum dose such as >20 morphine equivalent) **b. Option 1:** Non-pharmacologic, evidence-based interventions (stretching/massage group education) in primary care clinic with case management to facilitate and promote engagement and long-term maintenance of activities at home **c. Option 2:** Similar curriculum/support offered by a community-based organizations several times weekly such as the YMCA. This program must be at no or low cost. Peer coach support to encourage engagement and maintenance of activities along with an incentive/competition for completion **d. Outcomes:** Function (e.g., 6 min walk test, sit to stand 5x) QoL, patient satisfaction, mental health (PHQ9, anxiety), pain (10 pt scale), change in dose of opioid repeated measures at 3,6, 12 months **e.** Study must involve a multidisciplinary team (primary care, pain specialty, PT, kinesiology, psychology/psychiatry) to insure that the interventions offer high levels of motivation and patient self-management education while coordinating closely with the primary care provider.
1.5	2) Opioid risk reduction in persons initiating opioids for chronic non-cancer pain **a. Population:** Patients with musculoskeletal pain who meet eligibility criteria for initiating opioid therapy (e.g, failed alternatives such as PT, non-opioid drugs, injections). This project must include vulnerable populations who are more likely to be undertreated for pain but who suffer disproportionately from pain (NHANES) including minorities and low income groups. **b. Option 1:** Patient-centered medical home structure that takes advantage of an EMR support package and case management to offer support and insure high quality care. The EMR must offer tools to evaluate risk of OAs (ORT) and monitor of total opioid dose/daily dose as well as concurrent treatment with potentially risky drugs such as psychotherapeutics (e.g. benzodiazepines, hypnotics), antidepressants. **c. Option 2:** low opioid dose therapy and referral to a practice-based pain champion – MD, PA, RN – who has received advanced training in an evidence based pain management program, Patient visits the clinic specialist at least every 6 months (to supplement care from a primary care physician). This arm offers basic EMR support (ORT, OA agreement) • Both arms offer collaborative care with appropriate specialists (PT, pain experts). **e. Outcomes:** Opioid dose, functional measures (6 min speed walk, 50ft speed walk, 5x sit to stand), mental health(PHQ 9) /mental functioning (symbol digit test) measures, pt satisfaction, measures of opioid misuse (early refill requests, dose escalation)

1.6	3) Cognitive behavioral therapy **a. Population:** Patient with chronic noncancer pain >3 months without achievement of functional goals **b. Option 1:** individual CBT directed by primary care clinic-based counselor (e.g. case manager trained in a pain management program – consider a refinement of the general CBT model such as the Acceptance and Commitment Therapy (ACT) 1) provided in person counseling biweekly alternating with phone call updates - supplemented by education/practice with meditation and stress management techniques in group therapy programs. Case manager collaborates closely with the primary care physician in developing a drug treatment program plan and encouraging adherence **c. Option 2:** patient referred to psychologist for CBT with informational support for meditation and stress management approaches **d.** In both arms patients are provided educational materials informing them that opioids are only one component of a pain treatment program that require other nondrug approaches to improve function. e. Similar to outcomes above but focus on empowerment, satisfaction, mental health conditions (e.g. PHQ9)
1.7	What is the benefit of chronic opioid treatment (COT) compared to self-care management for patients with chronic pain for whom primary care providers are considering initiating COT? Using a 2x2 factorial design would allow one to examine both of these as individual modalities a well as their combination with usual care.
1.8	For patients with chronic pain already established on opioid therapy, are more intensive specialty-based interdisciplinary services superior for reducing patients' reliance on opioids and facilitating improvements in functioning/QOL when compared to evidence-based multimodal services that can be feasibly delivered in closer connection with primary care clinics/clinicians?

2	**Risk Assessment and Risk Mitigation Strategies:** In patients with chronic pain being considered for long-term opioid therapy, what is the accuracy of various instruments in predicting risk for opioid overdose, addiction, abuse, or misuse?
2.1	What are the benefits and risks of assessing adults with chronic pain syndromes for coexisting behavioral health disorders and substance abuse disorders before initiating long term opioid treatment versus not assessing for those disorders?
2.2	For patients with chronic non-cancer pain, who have been on long-term opioid therapy, what is the comparative effectiveness of risk mitigation strategies 1) opioid management plans, 2) patient education, 3) urine drug testing 4) prescription drug monitoring 5)monitoring instruments 6) more frequent monitoring intervals 7) pill counts 8) use of abuse-deterrent formulations on outcomes related to overdose, addiction, abuse, or misuse?
2.3	Compared with other medications for various illnesses, through DNA testing can people be identified who will or won't respond to opioid pain relievers? The intended outcome: Identify patients who will benefit from opioid therapies which will diminish the possibility of prescribing these drugs for people who will not benefit, decrease addiction and overdose complications, and protect healthcare providers who treat chronic pain patients.

2.4	What are the comparative benefits and risks of pain versus no pain contracts for individuals with chronic pain utilizing chronic opioids?

3	**Other:** What is the comparative effectiveness of treatment strategies for managing patients with addition to prescription opioids on outcomes related to overdose, abuse, misuse, pain, function, quality of life?
3.1	How effective is the use of technology in community based transition programs for youth and young adults (15-25) in managing chronic pain and mitigating risk of opioid dependence compared to traditional transition programs?